IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF ROBERT D. MOORE, D.O.

Robert D. Moore, D.O. seeks to offer various opinions regarding the ability of the TVT-O mesh product to cause the injuries alleged by several plaintiffs in this litigation. Certain of these opinions are inadmissible under this Court's own rulings, Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). These opinions include:

- **Opinion that TVT-O causes various complications**. Dr. Moore appears to base his general opinion that TVT-O causes complications on a study he and his partner conducted. This study, however, is scientifically flawed because, as Dr. Moore concedes, it includes products other than the TVT-O and they failed to take those product differences into account when classifying the complications data. Without accounting for this error and bias, the study is scientifically flawed. To the extent he relies on this study to support his general complications opinion, this opinion should be excluded because it is the result of an unreliable methodology.

- **Opinions that the blind passage of trocars makes the TVT-O unreasonably dangerous, and that Ethicon failed to adequately warn and train physicians.** These are legal conclusions that are within the province of the jury, not an expert witness.

- **Opinion that TVT-O causes pain.** Dr. Moore merely recites an inadmissible narrative history of the development of TVT-O without, admittedly, citing to any medical literature or other reliable basis to support this opinion. To the extent that Dr. Moore relies on this narrative history to support his general pain opinion, this opinion should be excluded.

- **Opinions that mesh implanted in the groin causes bladder/bowel complications and "pain syndromes."** Dr. Moore relies on certain studies to support these opinions, but several of these studies do not support these opinions. To the extent he relies on these studies to support his pain-syndrome opinions, these opinions should be excluded because they result from an unreliable methodology.

- **Opinion that the inside-out surgical technique is a design defect.** A surgical technique is not a product. Alternatively, this opinion is unreliable because Dr. Moore relies on studies that do not support his design-defect opinion and it is otherwise the result of an unreliable methodology.

- **Opinion that the Abbrevo is a safer-alternative product.** Dr. Moore admits that the Abbrevo was not available as an alternative product before July 1, 2010. This product therefore cannot serve as a feasible alternative to prove design defect before that time.

- **Opinions as to what an adequate IFU should have contained.** Dr. Moore's opinion is premised on what he claims Ethicon knew and how it conducted itself based on his review of company documents. His adequacy opinions are otherwise inadmissible because they are based on an unreliable methodology.

- **Opinions involving physician training and the competency of other physicians.** These opinions are unreliable, irrelevant, speculative, and misleading.

- **Opinion that clinical trials show "unacceptable" complications.** Dr. Moore identifies no reliable methodology for determining what constitutes "unacceptable" complications and instead relies on his interpretation of company documents as to what Ethicon knew or how it conducted itself to support a marketing opinion he is unqualified to render.

- **Opinions relating to Ethicon's motive, knowledge, and intent.** This Court has repeatedly excluded this type of opinion testimony in other cases.

As more fully explained below, Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) ask that these opinions be excluded.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Moore's opinion that TVT-O causes various complications should be excluded to the extent it is based on a flawed study he conducted.

In his report, Dr. Moore references three articles he and his partner John Miklos authored based on studies they conducted. Dr. Moore claims these studies "are the largest known studies in the world on mesh complications and female reconstructive surgery" and "the largest published manuscript in the world on the subject of mesh complications and female urogenital surgery." Ex. C, Moore Report at 6. In reality, the three articles represent the same patient population studied and are merely subanalyses of the main publication—*The IUGA/ICS classification of synthetic mesh complications in female pelvic floor reconstructive surgery: a multicenter study*. Ex. D, Moore 4/15/16 Dep. Tr. 51:1-53:2.[1]

Even so, the main study is scientifically flawed and cannot support Dr. Moore's opinion that TVT-O causes various complications. The study included products other than the TVT-O (*id*. at 58:7-17), and Dr. Moore admits they failed to take into account the type of sling removed or whether the removed slings were from a product like TVT-O, which uses an inside-out technique (*id*. at 94:20-21), versus another product using an outside-in technique (*id*. at 58:23-59:23). He readily admits that he does not know "how many numbers of patients that we actually have identified inside-out versus outside-in." *Id*. at 60:4-6. And even more importantly, he admits that this study did not draw any conclusions that pain as a complication was worse in patients with a product using an inside-out technique compared to any other sling or how the mesh was causing pain. *Id*. at 60:7-17.

This Court has repeatedly held that an expert who fails to control for error and bias when conducting studies of explanted mesh renders any opinion that expert seeks to offer based on

[1] The three articles referenced in Dr. Moore's Rule 26 Report are attached as Exhibits E, F, and G to Ethicon's Motion to Exclude General-Causation Testimony of Robert D. Moore, D.O.

those studies excludible under *Daubert* because the opinion is not the result of a reliable methodology. *See Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D.W. Va. Jan. 15, 2014); *see also Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 687 (S.D.W. Va. 2014); *Hall v. Boston Scientific Corp.*, No. 2:12-cv-08186, 2015 WL 868907, at *25 (S.D.W. Va. Feb. 27, 2015). Dr. Moore admittedly can draw no conclusions that any of the complications he and his partner report are attributable to the TVT-O because they failed to institute any controls that would give a breakdown of the incidence of complications by product. Without those controls, they could draw no reliable product-specific conclusions, which Dr. Moore admits. *See* Ex. D, Moore 4/15/16 Dep. Tr. 60:7-17. To the extent that Dr. Moore's complications opinions rely on this study, those opinions should be excluded.

II. Dr. Moore's impermissible legal conclusions should be excluded.

This Court has made clear on numerous occasions that drawing legal conclusions is within the province of the jury, not the subject of expert testimony. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *see also Eghnayem*, 57 F. Supp. 3d at 691.

Despite this well-established rule of law, Dr. Moore seeks to offer the following legal conclusions:

- The blind passage of the trocars during implantation make the TVT-O unreasonably dangerous (Ex. C, Moore Report at 26-27);
- Ethicon failed to adequately warn about known problems with the TVT-O (*id*. at 28); and
- Ethicon inadequately trained physicians (*id*. at 39).

Consistent with the Court's earlier rulings, Dr. Moore should be precluded from offering these legal conclusions.

III. Dr. Moore's opinion that the TVT-O causes pain, bladder, bowel, and sexual dysfunction based on a narrative history of TVT-O is unreliable.

Dr. Moore opines that defects in the design of the TVT-O cause pain, bladder, bowel, and sexual dysfunction. Ex. C, Moore Report at 9-10. Instead of premising this opinion on some reliable methodology, Dr. Moore instead gives a narrative history of the TVT-O. *Id*. A narrative history of product development, however, is not proper expert testimony. *In re C.R. Bard*, 948 F. Supp. 2d at 646. Dr. Moore admits that he provides no support for this opinion, although he claims he does later in his report. Ex. D, Moore 4/15/16 Dep. Tr. 74:22-75:23. To the extent he relies on the narrative history as support for this opinion, it should be excluded.

IV. Dr. Moore's opinion that mesh causes various complications is based on speculation and is unreliable.

A. His groin- and thigh-pain opinions are speculative.

Dr. Moore seeks to testify that the transverse arms of the TVT-O "*may* compromise bladder/bowel function," among other complications. Ex. C, Moore Report at 10-11 (emphasis added). He also claims that groin and thigh pain "has been shown to statistically happen more often with transobturator approach" when compared to other approaches such as the retropubic TVT approach. *Id*. at 11. He premises these pain opinions on a database review by Cochrane, yet he admits that the Cochrane review is merely reporting statistics and does not give an explanation as to cause. Ex. D, Moore 4/15/16 Dep. Tr. 78:24-79:10.

He could point to no particular scientific study to support his opinion that the mesh causes the complications he claims and instead merely said that there were "many, many articles that describe chronic pain in this region secondary to TVT-O slings, and many come up with scientific reasoning behind it." *Id*. at 79:18-24. These "many, many" articles, however, are admittedly written in terms of possibilities, not probabilities. *Id*. at 80:1-81:7. He explains that

the use of the term "may" is merely semantic and a function of the rigor required by scientific journals.

> Well, I think that basically journal articles, and journals themselves, the verbiage that is required is different. That is what that particular author is stating. They also would state that if the mesh wasn't there, certainly the patient wouldn't have pain in that specific location.
>
> So there's been multiple studies that have looked at anatomical directions of this mesh, where it's going, the TVT-O in relationship to the obturator nerves. Also saying why are these patients in the TVT-Os having more groin pain than those that don't have mesh in that specific area.
>
> And so although they may say "may" or "perhaps" or "theoretically," which is verbiage that journals, medical journals require, it's in my opinion, to a medical degree of certainty, that this is what's causing these complications.

Id. at 80:13-81:7; *see also id*. at 92:19-23 (testifying that medical journals require a higher standard and require certain "verbiage"); *id*. at 98:18-99:4 (same).

Dr. Moore's artful transformation of "may cause" into "caused" turns the scientific method on its head. The rigor required by a scientific journal for publication is not "verbiage" required by the journal's editorial staff but the very foundation of the scientific method. As *Daubert* and this Court have made clear, an expert must employ "'in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field . . . .'" *Eghnayem*, 57 F. Supp. 3d at 675 (quoting *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). When the expert employs a lesser standard in the courtroom than he or she would in practice, as Dr. Moore does here, those opinions are excludible under *Daubert*. *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *10 (S.D.W. Va. May 6, 2015) (excluding Dr. Blaivas's safety opinion because he "phrase[s] [his] words differently in the peer-reviewed literature than [he] do[es] in the legal literature because it's two

different sets of rules"); *accord Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *15 (S.D.W. Va. May 5, 2015); *Frankum v. Boston Scientific Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at *13 (S.D.W. Va. May 1, 2015).

Dr. Moore's thigh- and groin-pain opinions here are no different than the flawed safety opinions offered by Dr. Blaivas in *Mathison*, *Wilkerson*, and *Frankum*. There is no different standard for peer-reviewed journals that justifies an expert transforming words of *potential* causation used in a scientific journal into words of *probable* causation. If this were so, the end result would be a more lenient standard to prove general causation in the courtroom than required of the expert in practice. This is not the law. Intellectual rigor is intellectual rigor regardless of the setting. Dr. Moore here lacks that intellectual rigor when he relies on studies that speak in possibilities as a confirmation of general causation. These studies provide no such support. Dr. Moore's thigh- and groin-pain opinions should be excluded.

B. His opinion that the TVT-O causes chronic pain is unreliable.

Dr. Moore seeks to testify that the TVT-O causes chronic pain not only in the groin and thigh, but also causes leg pain, pelvic pain, and nerve pain. Ex. C, Moore Report at 11. He relies on a study conducted by R. Teo, titled *Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women*,[2] which he claims was "actually stopped . . . because of excess pain reports in the TVT-O arm." *Id*. at 11-12. He will testify that the investigators "concluded it was no longer ethical to use the TVT-O device given the clear negative impact on patient health." *Id*. at 12.

Ethicon acknowledges that an expert's review of the scientific literature is an acceptable methodology, but the literature cited must support the expert's opinions. *See Sanchez v. Boston*

[2] This article is attached as Exhibit H to Ethicon's Motion to Exclude General-Causation Testimony of Robert D. Moore, D.O.

Scientific Corp., No. 2:12-cv-05762, 2014 WL 4851989, at *17 (S.D.W. Va. Sept. 29, 2014) (excluding Dr. Margolis's infection-rate opinion where he relied on a study that did not support his opinion); *see also Eghnayem*, 57 F. Supp. 3d at 678-79 (same); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 524 (S.D.W. Va. 2014) (same). Dr. Moore's opinion that the Teo study was stopped because of pain is not supported by the plain language of the Teo study. Ex. H, *Randomized Trial* at 1351 ("[W]e decided to stop recruitment before the full calculated sample was recruited since it was deemed that clinical equipoise had been lost."); *id*. at 1354 ("We stopped our study early based on this growing evidence of equal efficacy for either procedure but a significantly increased incident of postoperative leg pain after transobturator insertion.").

Dr. Moore also seeks to testify that Teo concludes that "it [is] no longer ethical to use TVT-O given the clear negative impact of patient health" and that the authors' "concluding message" was to recommend "retropubic tape placement to avoid a high incidence of leg pain." Ex. C, Moore Report at 12, 40. Even though Dr. Moore's report sets off this "concluding message" as if it taken from the Teo article, he could point to no place in that article where this recommendation was made. Ex. D, Moore 4/15/16 Dep. Tr. 86:21-87:20.

Nor could he identify anywhere in that article that the authors said it was unethical to use the TVT-O product. Instead, the authors stated, following the statement that clinical equipoise had been lost, that they "believed it was no longer ethical to randomize women to the TVT-O arm in light of these published studies," although "data on women already recruited would be of value in future systematic reviews and meta-analyses." Ex. H, *Randomized Trial* at 1351-52. These authors did not conclude that it was unethical to use the TVT-O product. That unsupported statement is merely Dr. Moore's *ipse dixit* as to what he thinks the authors believed. Ex. D,

Moore 4/15/16 Dep. Tr. 85:22-86:11. But even this unsupported belief is not based on a reliable foundation. The authors' conclusion, it is entirety, states:

> Short-term cure rates at 6 months are similar for the 2 procedures. TVT-O results in a higher level of postoperative and leg pain, although these problems are transient. Our findings are similar to those in other studies comparing retropubic and transobturator tapes. The 2 procedures have a high cure rate with low rate of complications.

Ex. H, *Randomized Trials* at 1355. Nothing in that conclusion supports his opinion that the authors concluded that it was unethical to use the TVT-O. Having a "high cure rate with low rate of complications" is the antithesis to Dr. Moore's unethical-to-use opinion.

More importantly, the Teo study does not address and did not study chronic pain. On the contrary, it looked at short-term pain—a fact Dr. Moore ultimately concedes. Ex. D, Moore 4/15/16 Dep. Tr. 88:14-89:16. At bottom, Dr. Moore's chronic-pain opinion is unsupported by the literature he cites and should be excluded on that basis.

V. Dr. Moore's inside-out technique opinion should be excluded as irrelevant.

A. A surgical technique is not a product defect.

Dr. Moore will testify that various aspects of the TVT-O *surgical technique* make the TVT-O defective in design, and increases the risk of nerve injury and pain. Ex. C, Moore Report at 13-18. He emphasizes that it is the technique, not necessarily the product itself that is defective in design because "[t]he technique is part of the product." Ex. D, Moore 4/15/16 Dep. Tr. 94:19.

Criticisms of surgical technique, however, cannot support a claim that an implantable medical device is defective in design. *Bogle v. Sofamor Danek Grp., Inc.*, No. 95–8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of

success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon") (emphasis added); *Sita v. Danek Med., Inc*., 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and noninstrumental spinal repair, not a defect in the product itself).

To the extent then that Dr. Moore's design-defect opinion is premised on criticisms of the inside-out surgical technique, that opinion is not relevant because a surgical technique is not a product design.

B. Dr. Moore fails to scientifically account for contrary studies.

As this Court has noted, an expert's opinion may be the result of an unreliable methodology if the expert "fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Eghnayem*, 57 F. Supp. 3d at 676 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005)). Here, Dr. Moore acknowledges the study led by P. Hinoul—*Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O)*[3]—references a study by Debodinance that found no difference in thigh pain between outside-in and inside-out techniques. Dr. Moore discounts the Debodinance study, however, because it is only "one study." Ex. D, Moore 4/15/16 Dep. Tr. 96:23-97:21; *see also* Ex. I, *Anatomical Variability* at 1205. Although Dr. Moore has not "completely ignored" contrary studies like Dr. Margolis did in *Eghnayem*, merely discounting a contrary study without giving a scientific basis for doing so is similarly based on an unreliable methodology. *See Sanchez*, 2014 WL 4851989, at *12-13

[3] This article is attached as Exhibit I to Ethicon's Motion to Exclude General-Causation Testimony of Robert D. Moore, D.O.

(finding Dr. Margolis gave no scientific basis for disagreeing with contrary studies and instead merely disagreed with them). That Dr. Moore "can probably quote more studies overall that show a higher rate of pain with inside-out TVT-O versus outside-in approach" (Ex. D, Moore 4/15/16 Dep. Tr. 97:18-21)—but then does not do so—is not a sufficient explanation for discounting the Hinoul study.

At bottom, Dr. Moore's opinion that the TVT-O causes pain because it is implanted via an inside-out approach is nothing more than improper post hoc ergo propter hoc reasoning. Indeed, he admits that his reasoning follows this syllogism: women experience pain, these same women had TVT-O implanted inside-out, therefore the pain is caused by the TVT-O. Ex. D, Moore 4/15/16 Dep. Tr. 102:2-18. This backward reasoning is illogical and contrary to the scientific method. *See, e.g., In re C.R. Bard*, 948 F. Supp. 2d at 605 n.4 (excluding expert's opinion premised "on the idea that because each bellwether plaintiff suffered pain after the mesh surgery, then the mesh must have caused the pain"). To the extent his inside-out surgical-technique opinion rests on this faulty logic, it should be excluded.

C. An alternative product is not a *feasible* alternative design if it could not be legally marketed when TVT-O was manufactured for sale.

Dr. Moore will testify that the Abbrevo mesh product is a safer alternative product and supports his inside-out design-defect opinion. Ex. C, Moore Report at 19. He relies on a multitude of internal Ethicon documents he claims show that Ethicon knew that the TVT-O was associated with pain and foreign-body reaction, and that the Abbrevo was developed to respond to those issues. *Id*. at 20.

Aside from Dr. Moore's reliance on internal company documents for his inadmissible opinions on what Ethicon knew or its motives, Dr. Moore admits that Abbrevo was not legally available on the market until July 1, 2010 and thus could not have been a feasible alternative

product for implantation before that time. Ex. D, Moore 4/15/16 Dep. Tr. 111:15-17. Even so, this opinion suffers from lack of reliability for another reason as well. Dr. Moore is critical of the TVT-O and claims Abbrevo is a safer alternative, yet he remains critical of passing needles through the groin, which is the technique associated with Abbrevo. *Id.* at 112:5-15. Abbrevo cannot be both a safer alternative to TVT-O but at the same time defective. This logical inconsistency underscores that Dr. Moore's safer-alternative opinion is not the result of a reliable methodology, but unreliable *ipse dixit*.

VI. Dr. Moore's warnings opinions are unreliable.

A. Warnings opinions based on corporate knowledge, conduct, or motives are not helpful to the jury and should be excluded.

Dr. Moore seeks to offer several warnings opinions, many of which are premised on Dr. Moore's review and regurgitation of Ethicon company documents that Dr. Moore claims show what Ethicon knew or how Ethicon conducted itself. Ex. C, Moore Report at 28-38. These opinions include:

- Opinions based on communications from Meng Chen "explain[ing] to Ethicon's upper management" Ethicon's current knowledge (*id.* at 30; *see also id.* at 35);
- Opinions based on documents reflecting what was "known or at least available to Ethicon" (*id.* at 30);
- Opinions claiming Ethicon knew that polypropylene was subject to degradation, and causes foreign-body reaction and chronic inflammation (*id.*);
- Opinions claiming that Ethicon knew about certain risks that should have been included or, if included, were understated (*id.* at 32, 34);
- Opinions that Ethicon considered modifying the TVT-O IFU (*id.* at 34);
- Opinions based on company communications about patient positioning (*id.* at 38); and

- Opinions that Ethicon failed to act a responsible medical device manufacturer (*id*. at 37), among others.

This Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because these matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis*, 2014 WL 186872, at *6, *21; *see also, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D.W. Va. 2014); *In re C. R. Bard*, 948 F. Supp. 2d at 611, 629; *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *4 (S.D.W. Va. Feb. 7, 2015). The Court has also excluded opinions that offer "simply a narrative review of corporate documents" because these "opinions" are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Sanchez*, 2014 WL 4851989, at *32 (same); *Edwards*, 2014 WL 3361923, at *10 (finding expert's explanation of company documents not helpful; the jury is capable of reading and interpreting the documents itself).

As in these cases, the jury here is equally capable of reading and interpreting company documents and drawing its own conclusions without the assistance of expert testimony. Any statements of corporate conduct, knowledge, and motives are not helpful to the jury and do not survive Rule 403 balancing. They should be excluded in their entirety.

B. Dr. Moore's opinion that the TVT-O IFU is inadequate because it does not include frequency, severity, and duration information is not only a legal conclusion, but also based on an unreliable methodology.

Dr. Moore will testify that the TVT-O IFU "did not adequately convey the frequency, severity and duration of the risks that were disclosed." Ex. C, Moore Report at 31. He relies on nothing more than his personal belief and preference that this information be included in the IFU. *Id*. He claims that "it's the surgeon's right to have that information at their hands" to relay to their patients. Ex. D, Moore 4/15/16 Dep. Tr. 133:9-14. He identifies no authority for this vague

"right" other than his personal belief and preference that this information be included in the IFU. Ex. C, Moore Report at 31.

Without any scientific support that this information should be included in the TVT-O IFU, Dr. Moore's opinion that the IFU is inadequate without this information is a legal conclusion within the province of the jury and should be excluded. *Wise*, 2015 WL 521202, at *4 n.4. This Court has also excluded this type of opinion testimony for lack of reliability where the expert can point to no support—and Dr. Moore provides none here—showing that a manufacturer should include frequency, severity, and duration of risk information in its IFU. *See Frankum*, 2015 WL 1976952, at *21 (excluding warnings opinion that frequency-severity information should be included in the manufacturer's IFU where there was no support that this information should be included). It should be excluded here as well.

C. His warnings opinion based on what other physicians did not know is speculative and unreliable.

Dr. Moore will testify that physicians were not aware of the risks he claims should have been included in the TVT-O IFU. Ex. C, Moore Report at 32. Dr. Moore identifies no authority for claiming to know what other physicians know or knew. Indeed, he conducted no survey of any kind but merely bases this opinion on "talking with them, and figuring out what they know and don't know . . . . " Ex. D, Moore 4/15/16 Dep. Tr. 138:16-139:13. This is not the intellectual rigor required of an expert's opinion but pure speculation. This opinion should be excluded.

D. His opinion that Ethicon should have included a diagram in the IFU is unreliable.

Dr. Moore will testify that the TVT-O IFU is inadequate because it does not include a diagram of proper patient positioning. Ex. C, Moore Report at 38. He claims internal company documents "suggest" including such a diagram, but otherwise cites no authority that a diagram is

required for an IFU to be adequate—or any authority at all that it should be included for that matter. *Id*.

This diagram opinion should be excluded for the same reason Dr. Galloway's alphabetization opinion was excluded in *Winebarger v. Boston Scientific Corp*.—it is nothing more than Dr. Moore's personal belief. No. 2:13-cv-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015) (finding expert's opinion that alphabetizing complications instead of listing them in order of importance rendered the manufacturer's Directions for Use inadequate was nothing more than the expert's personal belief).

VII. Dr. Moore's inadequate-physician-training opinion is an opinion about the competency of other physicians, and is irrelevant and speculative.

Dr. Moore claims that Ethicon's physician training is inadequate with respect to "average" surgeons and that the inadequate training provided was a means to increase revenue. Ex. C, Moore Report at 39. He premises this opinion on internal company documents that purport to show Ethicon's corporate conduct and, as discussed, is excludible on this basis.

This opinion is also excludible to the extent that it calls on Dr. Moore to offer testimony about the competency of other physicians. This Court has already ruled that opinions regarding the competency of other physicians are irrelevant and will not assist the jury. *Edwards*, 2014 WL 3361923, at *17. It should do the same here.

VIII. Dr. Moore's unacceptable-complications opinion is speculative, unreliable, and unhelpful, and he is not qualified to render a marketing opinion.

Perhaps recognizing that his unacceptable-complications opinion suffers from lack of support and should be framed differently (Ex. C, Moore Report at 39, Part II.D), Dr. Moore seeks to offer marketing opinions under the guise of a clinical-trial opinion. Indeed, he will testify that Ethicon developed the TVT-O in "'record time' without conducting a clinical study" to "avoid losing market share to competing products already on the market." *Id*. at 39-40.

This "marketing" opinion should be excluded for four reasons. First, Dr. Moore has demonstrated no experience in marketing that qualifies him to render what amounts to a marketing opinion. *See In re C.R. Bard*, 948 F. Supp. 2d at 614 (excluding Dr. Shull's opinion that sought to show Bard acted improperly in its marketing). Second, Dr. Moore's opinion is based on internal company documents that need no expert interpretation and is therefore unhelpful for the jury. Third, Dr. Moore again relies on the Teo study already discussed earlier in Section IV(B) to support his unethical-to-use-TVT-O opinion when Teo concludes no such thing. And last, he fails to identify any methodology for what constitutes "unacceptable" rates of complications. Instead, this opinion is no more than *ipse dixit*, or a personal opinion, and should be excluded on that basis. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Sanchez*, 2014 WL 4851989, at *31-32 (finding subjective and conclusory approach to opinion demonstrated mere speculation and personal belief warranting exclusion of the opinion as unreliable).

CONCLUSION

For these reasons, Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Robert D. Moore, D.O.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 2, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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